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EXAMINER	
ELLIS, J	7
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WILLIAM S. FROMMER, ESQ.
CURTIS, MORRIS & SAFFORD
530 FIFTH AVENUE
NEW YORK, NY 10036

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 5/4/92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 22-32 are pending in the application.
   Of the above, claims 24-28, 30 & 31 are withdrawn from consideration.
2. ☒ Claims 1-21 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 22, 23, 29 & 32 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 22-32 are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

This application contains claims directed to the following patentably distinct species of the claimed invention: thymidine kinase, claims 24 and 25; herpes simplex virus glycoprotein, claims 26, 27, 29, and 30; influenza virus hemagglutinin, claims 26, 28, 29, and 31; and hepatitis B virus surface antigen, claims 29 and 32.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 22 and 23 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

During a telephone conversation with Mr. T. Kowalski on January 6, 1993 a provisional election was made with traverse to prosecute the species of hepatitis B surface antigen, claims 22, 23, 29, and 32. Affirmation of this election must be made by applicant in responding to this Office action. Claims 24-28, 30, and 31 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected species.

The Form PTO 1449 submitted in Paper No. 6, lists 4 U.S. Patents and 53 journal publications as relevant prior art; however, only the 4 U.S. Patents were attached to the list of references and are currently of record in the file. Applicants are kindly requested to submit copies of those references they would like to have considered by the Examiner in the prosecution of the instant application.

Claims 22, 23, 29, and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19; 1-12; 1-7; and 1-4 of U.S. Patent Nos. 4,769,330; 4,603,112; 4,722,848; and 5,110,587. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to isolate the expressed "gene products" taught by the referenced Patents.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to

prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 22, 23, and 29 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

The claimed invention is directed to any "gene product", protein, or antigen "from expression by a recombinant vaccinia virus" however, it fails to demonstrate a patentable utility for said products. The specification fails to provide substantive evidence of an actual biological function or activity of the claimed gene products. It is well known that a compound must have an established utility at the time of filing an application and not merely be potentially useful or under investigation by scientific researchers. In Brenner v. Manson, 148 USPQ 689, the Supreme Court held:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point- where specific benefit exists in currently available form- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The Court further stated:

> [t]hese arguments for and against the patentability of a process which either has no known use or is useful only in the sense that it may be an object of scientific research would apply equally to the patenting of the product produced by the process.

Assertions such as "therapeutic agents" (In re Lorenz, 134 USPQ 312), for "pharmaceutical purposes", (In re Diedrich, 138 USPQ 128), and "biological activity" (In re Kirk, 153 USPQ 48; Ex parte Lanham, 135 USPQ 106) are insufficient to establish the utility of a compound. In addition, applicants cannot rely on the fact that homologous or similar compounds possess a particular biological activity. See Brenner v. Manson. In the instant case, the specification fails to demonstrate any patentable utility for the claimed "gene products", proteins, or antigens.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure.

The specification teaches the construction of several recombinant vaccinia viruses which are capable of expressing heterologous proteins on their surface; i.e., the production of modified vaccinia viruses or vaccinia mutants. The specification fails to teach (i) that said heterologous proteins are secreted and exist as a product which is separate and distinct from the viral particle, or (ii) a method of constructing a recombinant vaccinia virus wherein any heterologous DNA sequence inserted into a non-essential region of the vaccinia virus genome results in the expression and secretion of a "gene product", protein, antigen, or hepatitis B surface antigen. The mere

expression of three heterologous proteins on the surface of vaccinia virus whose respective DNA sequences have been inserted into the HindIII-F fragment of said virus, fails to enable a generic claim to any protein product expressed by inserting a heterologous DNA sequence into any nonessential region of any vaccinia virus. Numerous factors effect protein expression such as protein cytotoxicity, differences in post-translational modifications, changes in the three dimensional conformation, mRNA stability, etc.. Accordingly, it is unpredictable which heterologous proteins can be expressed using a vaccinia virus vector. In addition, the expression and secretion of a heterologous protein requires the use of specific expression regulatory elements such as promoters and signal sequences in order to generate the production of a gene product which is distinct from the virus itself. The specification fails to teach any regulatory elements that induce protein secretion. Accordingly, the specification fails to enable one of ordinary skill in the art to express and secrete any heterologous gene product, protein, antigen, hepatitis B surface antigen.

Claims 22, 23, 29, and 32 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 22, 23, 29, and 32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is vague and indefinite in the recitation of a "gene product from expression by a recombinant vaccinia virus". It is not clear what "gene products" or mechanisms of expression applicants intend. It is unclear

whether applicants intend a "product" which is expressed by, and distinct from, the vaccinia virus, or a "product" which is expressed on the surface of the recombinant vaccinia virus. If applicants intend the latter, then this would raise issues with respect to statutory double patenting between all the elected claims of the instant case and Patent Nos. 4,603,112 and 5,110,587. Assuming arguendo, that applicants intend the gene product of claim 22 to be a protein product expressed by the recombinant vaccinia virus, claims 22 and 23 are duplicative in scope since only proteins are produced when DNA is expressed in any cell. When two claims in an application are duplicates, or are so close in content that they both encompass the same subject matter, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. MPEP §706.03(k). Therefore, should the indicated claims be found allowable, the duplicate claims will be rejected under 35 U.S.C. §101.

Claim 23 is vague and indefinite in the recitation of a "protein". It is not clear what proteins applicants intend.

Claim 29 is vague and indefinite in the recitation of an "antigen". It is not clear which antigens applicants intend.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22 and 23 are rejected under 35 U.S.C. § 102(b) as being

anticipated by Itakura et al., Badgy et al., Cohen et al., or Baxter et al..

Itakura et al., Badgy et al., Cohen et al., and Baxter et al. teach the isolation or production of proteins which are identical to the gene products or proteins claimed in the instant case. Applicants should note that since the claims read on any known protein regardless of its source the cited prior art meets all the elements of the claims.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 22, 23, 29 and 32 are rejected under 35 U.S.C. § 102(e) as being anticipated by McAleer et al., U.S. Patent No. 4,088,748; Funakoshi, U.S. Patent No. 4,113,712; McAleer et al., U.S. Patent No. 4,129,646; Andersson et al., U.S. Patent No. 4,138,287; Mizuno et al., U.S. Patent No. 4,162,192; or Murray et al., U.S. Patent No. 4,710,463.

McAleer et al., Funakoshi, McAleer et al., Andersson et al., Mizuno et al., and Murray et al. teach the isolation of hepatitis B surface antigen (HBsAg). Absent evidence to the contrary, the HBsAg taught by the references is identical to the gene products, protein, antigen and HBsAg of the instant case.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Ellis whose telephone number is (703) 308-3990.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Ellis, Ph.D.
January 7, 1993

JOAN ELLIS
PRIMARY EXAMINER
GROUP 180